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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/776,786	05/01/1997	MARTINE BARKATS	ST94065-US	2477

7590

01/31/2003

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 01/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/776,786

Applicant(s)

Barkats et al.

Examiner
Scott D. Priebe, Ph.D.

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 25, 2002
- 2a) ☒ This action is **FINAL**.
- 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27, 34-36, 38, 40, 41, and 48-50 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27, 34-36, 38, 40, 41, and 48-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27, 34, 35, 36, 38, 40, 41, 48 and 49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over French et al., US 6,290,949 (with priority to at least 9/1/93) in view of Mullenbach et al. UCLA Symp. Mol. Cell. Biol., New Ser., v. 82, pp. 313-326 (1988) for the reasons of record set forth in the Office action of 6/24/02.

Applicant's arguments filed 11/25/02 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the only reason that French does not anticipate the invention on its face, is that French does not explicitly teach that the glutathione peroxidase encoded on the vector be human. Motivation to combine can be found within the knowledge of one of ordinary skill in the art. In this case, common sense dictates that if one is going to introduce a gene into an organism

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to supplement or overcome a deficiency, that one use the gene endogenous to that species, in this case the human glutathione peroxidase. Mullenbach shows that the DNA required to encode the human glutathione peroxidase was known in the art. Consider the obverse, why would one of skill in the art choose to deliver a bovine glutathione peroxidase DNA to a human patient if the human DNA was known. In addition, applicant has not challenged that one of ordinary skill in the art was not aware of the potential for immune response against a foreign therapeutic gene, e.g. using a bovine glutathione peroxidase in a human patient, only that the references cited did not teach the concept. Applicant is reminded that specifications preferably omit common knowledge in a subject area. Such omission does not mean that one of ordinary skill in the art is unaware of common knowledge. With respect to adenoviral vectors lacking E1 and at least one of E2, E4 or L1-L5, French teaches using adenoviral vectors in which all adenoviral coding sequences have been removed (col. 12, lines 24-34). Clearly if all adenoviral coding sequence is absent, including the E2, E4, and L1-L5, the genes are non-functional.

Claims 27, 34-36, 38, 40, 41, and 48-50 remain rejected under 35 U.S.C. 102(e)/103(a) as being unpatentable over Ohya et al., US 5,187,078, in view of McClelland et al., U.S. 5, 543,328 for the reasons of record set forth in the Office action of 6/24/02.

Applicant's arguments filed 11/25/02 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

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combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant appears to argue that it would only have been obvious to try to make an adenoviral vector with the glutathione peroxidase DNA because McClelland did not explicitly teach incorporating it into their adenoviral vector. This argument fails to take into account the combination of references. Ohya teaches the desirability of delivering a human glutathione peroxidase to cultured cells and McClelland teaches that adenoviral vectors are particularly advantageous for such purposes.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

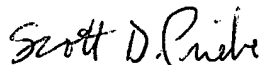
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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Primary Examiner
Technology Center 1600
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